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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,048	12/27/2001	Ernst Heinz	0093/000032	5170
26474 7590 11/16/2007 NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005			EXAMINER GUZO, DAVID	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/019,048

Applicant(s)

HEINZ ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/4/07 has been entered.

### **Election/Restriction**

Claims 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/10/03.

### **Priority**

**Priority for the claimed invention is granted back to the filing date of the PCT/EP00/06223 application, filed 7/04/2000.** Support for the instant claims is not found in the US 09/347,531 (hereafter the '531 application) application and since an English translation of the German application 100 30 976.3 has not been provided, priority cannot be granted back to the filing date of the German document. Specifically, support for the limitations in claims 1, 9, 14 and 15, with regard to the genus of nucleic acids encoding derivatives of SEQ ID NO:1 is not found in the '531 application. Also, no

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support for the percent homology limitations in claims 1, 9, 14 and 15 is found in the '531 application, no support for the at least 1 mol% of unsaturated fatty acids is found in the '531 application, etc.

### **Specification**

The disclosure is objected to because of the following informalities: Numerous pages have the terminology "[sic]" and "[lacuna]" inserted in the text. This terminology does not appear to have any meaning in the specification and should be deleted.

Appropriate correction is required.

### **Sequence Rules**

Applicants' submission of 7/31/07 places the application in compliance with the Sequence Rules.

### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 13-14 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Girke et al. (previously applied).

Applicant's invention is drawn to a process of preparing unsaturated fatty acids and to transgenic organisms, wherein the process utilizes or the organisms comprise at least one isolated nucleic acid of a sequence encoding a polypeptide with  $\Delta 6$ -desaturase (D6D) activity that is selected from the nucleic acid of SEQ ID NO: 1 (isolated from *Physcomitrella patens*), as well as nucleic acids that are derivatives of SEQ ID NO: 1 in the context of degeneracy of the genetic code where said derivatives encode a polypeptide having the requisite D6D activity or sequences encoding a polypeptide having at least 90 or 95% homology at the amino acid level, etc.

Girke et al. (Plant J., July, 1998, Vol. 15(1), pp. 39-48) teach identification and expression of a  $\Delta 6$ -desaturase (D6D) from *P. patens* (PPDES6). (e.g., Abstract). At minimum the reference teaches sequences that are derivatives of SEQ ID NO: 1 or encoding polypeptides that share at least 90% sequence identity with sequences shown in SEQ ID NO: 2. (e.g., Figure 1; depicting PPDES6). Furthermore, the reference teaches that the cDNA for PPDES6 is 2012 bp, i.e., SEQ ID NO: 1. (e.g., p. 40, col. 1, last full paragraph). The amino acid sequence disclosed for PPDES6 is the same as that of SEQ ID NO: 2 (Id.).

In addition, the reference teaches expression of PPDES6 in *S. cerevisiae*. (e.g., p. 45, col. 2, ¶ 3; claims 1, 4, 9). Furthermore, expression of PPDES6 in the cells (i.e., cultured cells) produces concentrations of unsaturated fatty acids (i.e., % total) that are at least 1 or 5%, whereby to measure the concentration of said fatty acids, each would have to be isolated from the yeast cells in the first place. (e.g., p. 45, col. 1, Table 1;

claims 1, 7-8). Additionally, PPDES6 is from *P. patens*, a moss, which in turn is a plant.  
(claims 2-3).

### 35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al. in view of Napier et al. (previously applied).

Applicants claim a process of preparing unsaturated fatty acids in organisms and to transgenic organisms wherein the organisms are plants (oil crops) and the transgenic organism is a plant.

The Girke et al. reference does not explicitly teach expression of PPDES6 in plants or oil crop. However, the reference implies that the desaturase, such as PPDES6 isolated from moss, is a good source for producing a wider variety of polyunsaturated fatty acids (UFAs). (e.g., p. 39, under "Introduction"). In any event, utilization of D6Ds to modify the lipid composition in oilseed crop was a primary focus in the art at the time of invention. For example, Napier et al. discuss utilizing desaturases from different sources for producing a wider variety and beneficial UFAs. (e.g., Abstract; p. 123). More particularly, the reference explicitly notes that the D6D isolated from *P. patens* is another D6D, in the same vein as producing fatty acids in transgenic oilseed crop. (e.g., p. 125, ¶ 1). The primary thrust of Napier et al. is that expression of desaturases in transgenic plants will lead to production of 'designer oil[s]' in said plants so as to meet the demands of the pharmaceutical and chemical industry. (e.g., p. 126, last paragraph).

Therefore, it would have been obvious to utilize the PPDES6 desaturase as taught by Girke in plants or oilseed crop. One would have been motivated to make such transgenic plants and to produce UFAs therein, so as to utilize PPDES6, with the benefit of extending the range of beneficial designer oils or UFAs produced. Furthermore, given the level of skill at the time of invention, there would have been a reasonable expectation of success in producing UFAs in a plant, transformed with PPDES6.

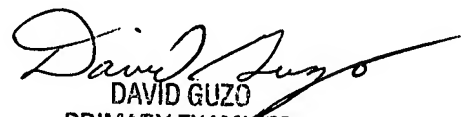
No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
DAVID GUZO  
PRIMARY EXAMINER

David Guzo  
November 2, 2007